REMARKS

Claims 1-28 currently appear in this application. The Office Action of May 31, 2001, has been carefully studied. It is believed that all of the claims are allowable, and favorable action is earnestly requested.

The amendments to the claims are of formal nature only, *i.e.*, made to eliminate multiple dependencies. The amendments are not "narrowing" amendments and are not made for any "substantial reason related to patentability." The scope of the claims has not been changed; no limitations have been added and none are intended.

The amendment to the specification in which 1×10^{7} was changed to 1×10^{17} was a typographical error. The corresponding numeral in the original PCT specification in Japanese was 1×10^{17}.

Objections

Claims 7-13 are merely objected to as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim.

The present amendment eliminates all multiple dependencies. Since claims 7-13 have not been rejected, it is respectfully submitted that these claims are now allowable.

Art Rejections

Claims 1-6, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holmes-Farley et al., U.S.

Patents 6,083,495; 5,496,545; or 5,667,775; each taken alone or in view of Goto et al. The Examiner alleges that the crosslinked polyallylamine resins of the instant claims are known to the art. The physical requirements for specific gravity, particle size, and comonomer ratio are said to be encompassed by the prior art synthetic enablement. Goto is said to described standard compression and coating steps for tablets.

This rejection is respectfully traversed. The phosphate-binding resins of the present invention have a true specific gravity of from 1.18-1.24, and are prepared by the process described on page 6, lines 22-27, and in "Preparation 1" on page 12, line 6 *et seq.* of the present specification, using a solvent consisting of a mixture of water and acetonitrile.

The resins disclosed by Holmes-Farley, on the other hand, were prepared using water alone as a reaction solvent in the crosslinking reaction. In "preparation 2" of the present specification, the crosslinking reaction was performed in the presence of water alone as the reaction solvent, the process of Holmes-Farley. As is clearly described, the true specific gravity of the phosphate-binding polymer prepared in "Preparation 2" was 1.253. This is clearly outside the range of the true specific gravity of the polymers of the present invention.

Holmes-Farley neither discloses nor suggests the use of a mixed solvent of water and acetonitrile for the crosslinking reaction. Thus, from Holmes-Farley, it would not be possible for one skilled in the art to prepare a resin having a true specific gravity of from 1.18 to 1.24. Goto adds nothing to this disclosure, as Goto merely discloses conventional tabletting procedures.

The Examiner alleges that the tablet of claim 10 contains the Holmes-Farley resin. Claim 10 has now been amended to make it clear that the resin has been crosslinked in a mixture of water and acetonitrile, because if the resin were crosslinked only in water the physical properties would not be those of claim 4, from which claim 10 depends. Since this limitation was inherent in claim 10 because of its dependency from claim 4, this amendment does not limit the claim in any way.

A resin prepared by the Holmes-Farley process, that is, by Preparation 2 of the present specification, has a true specific gravity outside the range of the resin claimed in the present application. Therefore, the tablet of claim 10 cannot possibly contain a resin of the prior art, as the properties of the resin of the present invention are different from the properties of the prior art resin.

The Examiner stated that the use of standard compression and coating steps, as described by Goto, could

obviously be applied to the product polyallylamine particles of Holmes-Farley. While it is true that these compression and coating steps can be applied to the Holmes-Farley resin, it is clear from the present specification that the results are not the same as with the resin of the present invention. Example 1 of the present invention compares the resin of the present invention, in which the true specific gravity was between 1.209 and 1.211, with the resin of Holmes-Farley, which had a true specific gravity of 1.253. It is clear from Example 1 that none of the tablets prepared using the Holmes-Farley resin had adequate hardness, while all of the tablets prepared using the resin of the present invention had adequate hardness.

It is respectfully submitted that the present specification as filed compares the resin of the present invention with the resin of Holmes-Farley, the closet cited prior art. It is self-evident that the resin of Holmes-Farley, which has a true specific gravity outside the ranges of the resin of the present invention, does not provide tablets with a sufficient hardness. It is not the specific conditions of compression that provide the superior tablets of the present invention, but rather the specific resin used. When the same compression conditions were used for the Holmes-Farley resin as for the resin of the present invention, it was clear that the tablets formed from the resin of the present

invention were superior to those formed from the resin of Holmes-Farley.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

Respectfully submitted,

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IN THE SPECIFICATION

Page 3, please amend the second paragraph as follows:

When administered orally, phosphate-binding polymers adsorb phosphorus in foods and are excreted into the feces to thereby inhibit the absorption of phosphorus via the digestive tracts, thus controlling the serum phosphorus level. These phosphate-binding polymers are taken in a relatively large single dose, i.e., from 1 to 2 g. Because ~~of reacting~~ they react with water and thus ~~swelling~~ swell rapidly, the phosphate-binding polymers can be hardly taken as such. What is more, tablets prepared by compressing the conventional phosphate-binding polymers without additives have only insufficient tablet hardness, so it has been essential to incorporate substantial amounts of crystalline cellulose and/or low substituted hydroxypropyl cellulose.

Page 4, please amend the first paragraph as follows:

Patients ~~with~~ on dialysis who need be administered the phosphate-binding polymers as remedies for hyperphosphatemia are often required to take in limited amounts of water. It is therefore required to develop phosphate-binding polymer preparations in dosage forms that

can be taken with small amounts of water. One of the promising dosage forms is tablets which can be reduced in size by compression and coated tablets are preferred since they will not disintegrate in the mouth and can be ingested smoothly. However, when processed into tablets by compressing, a phosphate-binding polymer alone gives only poor tablet hardness and thus cannot be processed as such into a tablet preparation. Further, due to the high hygroscopicity and swelling properties of the phosphate binding polymer, it is also impossible to produce a phosphate-binding polymer preparation by a process comprising wet granulation using water or a binder solution containing alcohols, etc. and subsequent drying.

Page 7, please amend the first paragraph as follows:

Since the phosphate-binding polymer of the invention is a crosslinked polymer, m in the above formula is a large integer that represents the network structure of the crosslinked and extended polymer and can theoretically be as great as 1 x ~~10^{7}~~10^{17}. Since this polymer is crosslinked in a network, each of the particles into which it has been ground is in effect a single molecule; therefore, the molecular weight of the polymer is equivalent to the weight of an individual polymer particle.

IN THE CLAIMS

6. (Amended) The tablet according to claim 4, ~~5 or 6,~~ wherein said particles of a phosphate-binding polymer have an average particle size of no more than 250 μm, with at least 90% being occupied by particles no larger than 300 μm.

7. (Amended) The tablet according to ~~any one of claims~~ claim 1~~—6~~, which further contains crystalline cellulose and/or low substituted hydroxypropyl cellulose.

9. (Amended) The tablet according to claim 7~~ or 8~~, wherein the low substituted hydroxypropyl cellulose has 5.0 - 16.0 wt% substitution by hydroxypropoxyl groups.

10. (Amended) The tablet according to ~~any one of claims~~ claim 4~~—9~~, wherein the phosphate-binding polymer is the one described in U.S. Patent No. 5496545 which has been **crosslinked in a solvent comprising a mixture of water and acetonitrile**.

12. (Amended) The tablet according to ~~any one of claims~~ claim 4~~—11~~ which further contains a hardened oil.

13. (Amended) The tablet according to ~~any one of~~

~~claims~~ claim 4~~-12~~ which is coated on the surface with a water-soluble film base.